Clinical trial results:
Randomized double-blind placebo-controlled trial on the efficiency of a single dose dexamethasone in reducing the postembolization syndrome in men undergoing prostatic artery embolization for benign prostatic hyperplasia

Summary

EudraCT number	2020-000915-53
Trial protocol	DK
Global end of trial date	03 November 2022

Results information

Result version number	v1 (current)
This version publication date	25 October 2024
First version publication date	25 October 2024

Trial information

Trial identification

Sponsor protocol code	DEXAPAE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04588857
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	The Department of Radiology and The Department of Urology, Rigshospitalet, +45 35458789, andreas.roeder@regionh.dk
Scientific contact	The Department of Radiology and The Department of Urology, Rigshospitalet, +45 35458789, andreas.roeder@regionh.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 November 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 May 2022
Global end of trial reached?	Yes
Global end of trial date	03 November 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Reduction in post-procedural fever and pain with dexamethasone in patients undergoing prostatic artery embolization (PAE) for benign prostatic hyperplasia (BPH)

Protection of trial subjects:

Participation in the trial was voluntary and did not affect the individual's assessment and treatment process. The participants were informed, both orally and in writing, of the study's purpose and implications. Prior to participation, the trial participants signed a consent form. Participants could withdraw their consent at any time without explanation. The standard clinical procedure was the same for trial participants.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	5
From 65 to 84 years	26

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All patients referred to the Department of Urology, Rigshospitaltet with lower urinary tract symptoms, and who were candidates for prostatic artery embolisation were considered for trial recruitment.

Pre-assignment

Screening details:

Inclusion criteria mimicked the standard PAE eligibility criteria at our institution. Exclusion criteria consisted of current urological contraindications to PAE, contraindications for catheter-based interventions and contraindications for high-dose steroid administration. Written informed consent was obtained from all participants prior to inclusi

Period 1

Period 1 title	Intervention (Overall period) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Active Arm

Arm description:

Received trial medicine dexamethasone 24 mg as a single intravenous bolus dose

Arm type	Active comparator
Investigational medicinal product name	Dexavit 4mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

24 mg, single dose

Arm title	Placebo arm

Arm description:

Received intravenous saline

Arm type	Placebo
Investigational medicinal product name	Sodium Chloride 0.9%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

6 ml, single dose

Number of subjects in period 1	Active Arm	Placebo arm
Started	16	15
Completed	16	15

Baseline characteristics

Reporting groups

Reporting group title	Intervention (Overall period)

Reporting group description: -

Reporting group values	Intervention (Overall period)	Total	
Number of subjects	31	31	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	70		
inter-quartile range (Q1-Q3)	66 to 75	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	31	31	

End points

End points reporting groups	
Reporting group title	Active Arm
Reporting group description: Received trial medicine dexamethasone 24 mg as a single intravenous bolus dose	
Reporting group title	Placebo arm
Reporting group description: Received intravenous saline	

Primary: Rectal temperature (in degrees Celsius) at 2 days following intervention	
End point title	Rectal temperature (in degrees Celsius) at 2 days following intervention
End point description:	
End point type	Primary
End point timeframe: 2 days following intervention	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Degree Celsius				
arithmetic mean (standard deviation)	37.19 (± 0.59)	37.54 (± 0.7)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Primary: Pain Severity score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure	
End point title	Pain Severity score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure

End point description:

End point type	Primary
End point timeframe: First 5 days following intervention	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	2.94 (± 2.1)	1.88 (± 1.36)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Placebo arm v Active Arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Primary: Pain Interference score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure

End point title	Pain Interference score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure
End point description:	

End point type	Primary
End point timeframe: First 5 days following intervention	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	2.97 (± 2.2)	2.04 (± 1.36)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Paracetamol dose for the first 5 days	
End point title	Paracetamol dose for the first 5 days
End point description:	
End point type	Secondary
End point timeframe:	
First 5 days following intervention	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Miligrams				
median (inter-quartile range (Q1-Q3))	1750 (1175 to 2450)	1600 (1000 to 2900)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Confidence interval

Secondary: Ibuprofen dose for the first 5 days

End point title	Ibuprofen dose for the first 5 days

End point description:

End point type	Secondary

End point timeframe:

First 5 days following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Miligrams				
median (inter-quartile range (Q1-Q3))	80 (0 to 160)	0 (0 to 306)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: C-reactive protein value at 2 days following the procedure

End point title	C-reactive protein value at 2 days following the procedure

End point description:

End point type	Secondary

End point timeframe:

Day 2 following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Miligrams per liter				
median (inter-quartile range (Q1-Q3))	10 (5 to 33)	108 (54 to 161)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS at day 2 post procedure

End point title	IPSS at day 2 post procedure

End point description:

End point type	Secondary

End point timeframe:

2 days post procedure

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	24.9 (± 6.9)	21.1 (± 6.8)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS at 5 days post procedure

End point title	IPSS at 5 days post procedure
End point description:	

End point type	Secondary
End point timeframe:	
Day 5 post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	23.9 (± 8.5)	23.3 (± 7.2)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Nausea in the first 5 days post procedure

End point title	Nausea in the first 5 days post procedure
End point description:	

End point type	Secondary
End point timeframe:	
First 5 days following intervention	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Yes/no	9	11		

Statistical analyses

Statistical analysis title	Pearsons’s Chi-squared test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Secondary: Dysuria in the first 5 days post procedure

End point title	Dysuria in the first 5 days post procedure

End point description:

End point type	Secondary

End point timeframe:

First 5 days following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Yes/no	14	13		

Statistical analyses

Statistical analysis title	Pearsons’s Chi-squared test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Secondary: Urinary tract infection in the first 5 days post procedure

End point title	Urinary tract infection in the first 5 days post procedure

End point description:

End point type	Secondary

End point timeframe:

First 5 days following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Yes/no	1	0		

Statistical analyses

Statistical analysis title	Pearsons’s Chi-squared test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Secondary: Hospital admission in the first 5 days post procedure

End point title	Hospital admission in the first 5 days post procedure

End point description:

End point type	Secondary

End point timeframe:

First 5 days following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Yes/no	1	0		

Statistical analyses

Statistical analysis title	Pearsons’s Chi-squared test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Secondary: Acute urinary retention in the first 5 days post procedure

End point title	Acute urinary retention in the first 5 days post procedure

End point description:

End point type	Secondary

End point timeframe:

First 5 days following intervention

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Yes/no	0	2		

Statistical analyses

Statistical analysis title	Pearsons’s Chi-squared test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Secondary: IPSS score at 1 month post procedure	
End point title	IPSS score at 1 month post procedure
End point description:	

End point type	Secondary
End point timeframe:	
1 month post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	13.3 (± 9.3)	13.9 (± 4.9)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS score at 3 months post procedure	
End point title	IPSS score at 3 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
1 month post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	11.1 (± 9.2)	10.9 (± 7.4)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS score at 6 months post procedure

End point title	IPSS score at 6 months post procedure
End point description:	
End point type	Secondary
End point timeframe: 6 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	14.2 (± 8.1)	12.3 (± 6.2)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Confidence interval

Secondary: International Index of Erectile Function (IIEF) score at 1 month post procedure

End point title	International Index of Erectile Function (IIEF) score at 1 month post procedure

End point description:

End point type	Secondary

End point timeframe:

1 month post procedure

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	15.4 (± 6.3)	16.4 (± 6.0)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS score at 3 months post procedure

End point title	IPSS score at 3 months post procedure

End point description:

End point type	Secondary

End point timeframe:

3 months post procedure

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	16.5 (± 6.4)	16.6 (± 6.9)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: IPSS score at 6 months post procedure

End point title	IPSS score at 6 months post procedure

End point description:

End point type	Secondary

End point timeframe:

6 months post procedure

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Points				
arithmetic mean (standard deviation)	15.4 (± 7.8)	15.7 (± 6.9)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Mean urinary flow at 3 months post procedure

End point title	Mean urinary flow at 3 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
3 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters per second				
arithmetic mean (standard deviation)	4.8 (± 2.9)	4.7 (± 2.1)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Mean urinary flow at 6 months post procedure

End point title	Mean urinary flow at 6 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
6 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters per second				
arithmetic mean (standard deviation)	4.1 (± 1.7)	4.7 (± 2.6)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Maximum urinary flow at 3 months post procedure

End point title	Maximum urinary flow at 3 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
3 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters per second				
arithmetic mean (standard deviation)	12.0 (± 5.9)	11.9 (± 6.0)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Maximum urinary flow at 6 months post procedure

End point title	Maximum urinary flow at 6 months post procedure
End point description:	
End point type	Secondary
End point timeframe:	
6 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters per second				
arithmetic mean (standard deviation)	11.3 (± 5.8)	11.6 (± 6.6)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Prostate volume at 3 months post procedure

End point title	Prostate volume at 3 months post procedure
End point description:	
End point type	Secondary
End point timeframe:	
3 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Cubic centimeters				
arithmetic mean (standard deviation)	80 (± 27)	89 (± 33)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Prostate volume at 6 months post procedure

End point title	Prostate volume at 6 months post procedure

End point description:

End point type	Secondary

End point timeframe:
6 months post procedure

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Cubic centimeters				
arithmetic mean (standard deviation)	76 (± 26)	72 (± 18)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Residual urine at 3 months post procedure

End point title	Residual urine at 3 months post procedure
End point description:	
End point type	Secondary
End point timeframe:	
3 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters				
median (inter-quartile range (Q1-Q3))	28 (5 to 57)	20 (0 to 57)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Residual urine at 6 months post procedure

End point title	Residual urine at 6 months post procedure
End point description:	
End point type	Secondary
End point timeframe:	
6 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Mililiters				
median (inter-quartile range (Q1-Q3))	49 (12 to 95)	55 (50 to 80)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Prostate specific antigen (PSA) at 1 month post procedure

End point title	Prostate specific antigen (PSA) at 1 month post procedure
End point description:	

End point type	Secondary
End point timeframe:	
1 month post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Micrograms per litre				
median (inter-quartile range (Q1-Q3))	6.1 (5.3 to 10)	6.4 (5.2 to 10)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm

Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Prostate specific antigen (PSA) at 3 months post procedure

End point title	Prostate specific antigen (PSA) at 3 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
3 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Micrograms per litre				
median (inter-quartile range (Q1-Q3))	5.3 (3.2 to 7.5)	5.3 (3.9 to 7.3)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Secondary: Prostate specific antigen (PSA) at 6 months post procedure

End point title	Prostate specific antigen (PSA) at 6 months post procedure
End point description:	

End point type	Secondary
End point timeframe:	
6 months post procedure	

End point values	Active Arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	15		
Units: Micrograms per litre				
median (inter-quartile range (Q1-Q3))	5.1 (3.9 to 8.8)	5.4 (4.5 to 7.9)		

Statistical analyses

Statistical analysis title	Independent t-test
Comparison groups	Active Arm v Placebo arm
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Confidence interval	

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Up to 6 months post intervention	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Frequency threshold for reporting non-serious adverse events: 1 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No serious adverse events (SAEs) have been observed or reported. and no non-serious adverse events (AEs) were recorded. The absence of non-serious AEs aligns with the study findings, as no participants reported any conditions meeting the criteria for classification as non-serious adverse events. The study was closely monitored to ensure compliance with regulatory guidelines.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38233575